UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,519	03/20/2006	Inge Dorthe Hansen	HOI-14302/16	5664

25006 7590 06/24/2009

GIFFORD, KRASS, SPRINKLE,ANDERSON & CITKOWSKI, P.C
PO BOX 7021
TROY, MI 48007-7021

EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
06/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,519	HANSEN, INGE DORTHE	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/11/08* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-35,38-57 and 59-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-35,38-57 and 59-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 12/11/08.

The amendment filed 12/11/08 affects the application, 10/560,519 as follows:

Applicant's request for reconsideration of the finality of the rejection of the last Office action mailed August 20, 2008 is persuasive in that the claimed invention is not obvious over Woitun et al. (DE 1959402 A) and Ozmen et al., therefore, the finality of that action is withdrawn. Applicants' arguments and amendment have overcome the rejections of the office action mailed 08/20/08.

1. However, a new ground(s) rejection is set forth herein below.
2. The responsive to applicants' arguments is contained herein below.

Claims 30-35, 38-57 and 59-61 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-35 and 38-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the phrase "symptoms associated with bacterial vaginosis". However, the claim is indefinite since it is unclear what constitutes or does not constitute an association or "associated" as recited in the claim. That is, is it unclear which symptoms can are considered associated to bacterial vaginosis and which are not considered associated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-35, 38-42, 53, 55 and 57 are rejected under 35 U.S.C. 102(b) as anticipated by Greco et al. (US 5,084,277).

In claim 30, applicant claims a method for the treatment and/or amelioration of one or more symptoms associated with bacterial vaginosis, comprising administering to an individual in need an effective amount of a medicament comprising a saccharide wherein the medicament includes less than 10^5 bacteria per dosage, and a) wherein the medicament comprises at least 75 percent by weight of said saccharide or b) wherein the medicament is a gel or suspension comprising at least 40 % by weight of said saccharide. Greco et al. disclose a method of administering to an individual a composition comprising a saccharide wherein the composition comprises at least 79.00 percent by weight of said saccharide to treat progesterone deficiency. Because the only step in the method is administration of a composition comprising a saccharide, it is deemed that administration of the composition disclosed by Greco et al. would have inherently performed the said treatment and/or amelioration of symptoms associated with bacterial vaginosis because it is the same composition given to the same group of patients (see col. 6, lines 1 to 50). Claims 31-35, 38-42 and are drawn to said method involving specific symptoms, saccharides (including lactose) and composition comprising specific percentage by weight of saccharide, specific cause and specific forms of said composition are also encompassed by this rejection since Greco et al. uses the same composition with percentage by

weight, the same saccharide of the same form (vaginal tablet) and dosage and the cause does not further limit the symptom treated (see col. 6, lines 1 to 50 and abstract). In claim 53, applicant claims a pharmaceutical composition for vaginal application, comprising a saccharide, the composition including less than 10^5 bacteria per dosage, and a) wherein said saccharide constitutes at least 75 percent by weight of said pharmaceutical composition or b) wherein the pharmaceutical composition is a gel or suspension and said saccharide constitutes at least 40 % by weight of said pharmaceutical composition. Greco et al. disclose applicant's composition for vaginal use comprising a saccharide (lactose), wherein said saccharide constitutes at least 79.00 percent by weight of said pharmaceutical composition (see col. 6, lines 1 to 50 and abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for vaginal application, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Claim 55 which is drawn to a kit-of-parts comprising the pharmaceutical composition as defined in claim 53 and at least one pH measurement means, for measuring vaginal pH, is anticipated by Greco et al. (see col. 6, lines 1 to 50). It should be noted that the kit does not add to the patentability of the composition claimed. It should be noted that it is well settled that "intended use" of a composition or product, e.g., for vaginal application, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Claim 57 which is drawn to the pharmaceutical composition according to claim 53, wherein said saccharide is the essential active component, is anticipated by Greco et al. since Greco et al. saccharide (lactose) is the same as applicants (see applicant claim 35) and should also be the same essential active component (see col. 6, lines 1 to 50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 54, 56, 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greco et al. (US 5,084,277).

Claim 54 is drawn to a kit-of-parts comprising the pharmaceutical composition as defined in claim 53 and an anti-fungal agent and/or an anti-bacterial agent for simultaneous, sequential or separate use. It should be noted that the kit does not add to the patentability of the composition claimed. It should be noted that it is well settled that "intended use" of a composition or product, e.g., for vaginal application, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Claim 56 is drawn to the pharmaceutical composition according to claim 53, wherein the composition further includes an effective amount of an anfi-fungal agent or an anti-bacterial agent.

Greco et al. disclose a composition comprising a saccharide wherein the composition comprises at least 79.00 percent by weight of said saccharide to treat progesterone deficiency.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared a composition comprising a combination of Greco et al.'s saccharide (lactose) and to place it in a kit with other medicaments or substances such as an antifungal or antibacterial in order to treat to treat progesterone deficiency by administering

Greco et al.'s saccharide (lactose) to an individual's vagina and to simultaneously, sequentially or separately treat associated conditions or other vaginal conditions such as bacterial vaginosis, based on need such as the number of conditions of the vagina and the type and severity of the condition.

One having ordinary skill in the art would have been motivated to prepare a composition comprising a combination of Greco et al.'s saccharide (lactose) and to place it in a kit with other medicaments or substances such as an antifungal or antibacterial in order to treat to treat progesterone deficiency by administering Greco et al.'s saccharide (lactose) to an individual's vagina and to simultaneously, sequentially or separately treat associated conditions or other vaginal conditions such as bacterial vaginosis, based on need such as the number of conditions of the vagina and the type and severity of the condition.

Claim 59 is drawn to a method of reducing vaginal pH to below 4.7, comprising administering to an individual in need an effective amount of a medicament comprising said saccharide. Claims 60-61 are drawn to the method of claim 59 wherein the vaginal pH is reduced to below 4.5 and further, wherein said vaginal pH is measured subsequent to said administering.

Greco et al. disclose a method of administering to an individual a composition comprising a saccharide wherein the composition comprises at least 79.00 percent by weight of said saccharide to treat progesterone deficiency (see col. 6, lines 1 to 50).

The difference between applicant's claimed method and the method of Greco et al. is that Greco et al. does not determine the vaginal pH. However, it is well known in the art that the normal pH of vaginal secretions is less than 4.5 and that an increase in vaginal pH can be caused

by conditions such as rupture of membranes in pregnancy and bacterial vaginosis. Thus, it is obvious to a skilled artisan to determine and monitor the vaginal pH during the treatment of progesterone deficiency with the said composition comprising a saccharide in order to determine and optimize the efficacy of said treatment especially since it is well known that an increase in vaginal pH can be caused by conditions such as rupture of membranes in pregnancy and bacterial vaginosis would alter the pH.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to determine and monitor vaginal pH including any change in pH such as a reduction or increase in said vaginal pH during the treatment of progesterone deficiency with the said composition comprising a saccharide in order to determine and optimize the efficacy of said treatment especially since it is well known that normal pH of vaginal secretions is less than 4.5 and an increase in vaginal pH can be caused by conditions such as rupture of membranes in pregnancy and bacterial vaginosis would alter the pH.

One having ordinary skill in the art would have been motivated to determine and monitor vaginal pH including any change in pH such as a reduction or increase in said vaginal pH during the treatment of progesterone deficiency with the said composition comprising a saccharide in order to determine and optimize the efficacy of said treatment especially since it is well known that normal pH of vaginal secretions is less than 4.5 and an increase in vaginal pH can be caused by conditions such as rupture of membranes in pregnancy and bacterial vaginosis would alter the pH. Also, it should be noted that Greco et al. administer the same composition by the same route to the same subject and therefore it should inherently have the same effect property of reducing the vaginal pH.

Response to Arguments

Applicant's arguments with respect to claims 30-35, 38-57 and 59-61 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
June 22, 2009.

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623